CLAIMS

What is claimed is:

1. A method of treating colon cancer or rectal cancer which comprises administering to a patient in need of such treatment a therapeutically effective amount of irinotecan, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, and a therapeutically effective amount of thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof.

2. The method of claim 1 wherein the cancer is primary or metastatic.

3. The method of claim 1 wherein the irinotecan, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 25 to about 750 mg/m^2, and the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 1000 mg.

4. The method of claim 3 wherein the irinotecan, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 500 mg/m^2, and the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 750 mg.

5. The method of claim 4 wherein the irinotecan, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 350 mg/m^2, and the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 200 to about 500 mg.

6. A method of increasing the dosage of irinotecan that can be safely and effectively administered to a patient, which comprises administering to a patient in need of such an increased dosage an amount of thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, that is sufficient to reduce a dose-limiting adverse effect associated with the irinotecan.

7. The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered prior to the administration of the irinotecan.

8. The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered simultaneously with the administration of the irinotecan.

9. The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered after the administration of the irinotecan.

10. The method of claim 6 wherein the dose-limiting adverse effect is selected from the group consisting of early-forming diarrhea, late-forming diarrhea, nausea, vomiting, anorexia, constipation, flatulence, leukopenia, anemia, neutropenia, asthenia, abdominal cramping, fever, pain, loss of body weight, dehydration, alopecia, dyspnea, insomnia, and dizziness.

11. The method of claim 10 wherein the dose-limiting adverse effect is early-forming diarrhea or late-forming diarrhea.

12. The method of claim 6 wherein the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 1 to about 2000 mg.

13. The method of claim 12 wherein the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 1000 mg.

14. The method of claim 13 wherein the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 750 mg.

15. The method of claim 14 wherein the thalidomide, or pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 200 to about 500 mg.

16. A method of increasing the therapeutic efficacy of irinotecan which comprises administering to a patient in need of such increased therapeutic efficacy an amount of thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, that is sufficient to increase the therapeutic efficacy of irinotecan.

17. The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered prior to administration of the irinotecan to the patient.

18. The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered during administration of the irinotecan to the patient.

19. The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable prodrug, salt, solvate, hydrate, or clathrate thereof, is administered after administration of the irinotecan to the patient.

20. A method of reducing or eliminating gastrointestinal toxicity associated with the administration of irinotecan in a human which comprises administering to a human in need of such reduction an effective amount of thalidomide.

21. The method of claim 20 wherein the thalidomide is administered prior to the administration of irinotecan.

22. The method of claim 20 wherein the thalidomide is administered to a patient undergoing irinotecan therapy.